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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,096	01/24/2005	Thomas Ehrhardt	BASF. 10027	9245

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EXAMINER	
SAIDHA, TEKCHAND	
ART UNIT	**PAPER NUMBER**
1652	

MAIL DATE	DELIVERY MODE
09/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,096	EHRHARDT ET AL.	
	Examiner	Art Unit	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-13,15,26 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-13,15,26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL REJECTION

1. Amendment after non-final filed 8/28/2007 is acknowledged. Claims 9-13, 15, & 26-27 are present in this application and are under consideration in this office action.

2. Applicant's amendment and arguments filed 8/28/2007, have been fully considered but they are not deemed to be persuasive. The reasons are discussed following the rejection(s).

3. Any objection or rejection of record which is not expressly repeated in this Office Action has been overcome by Applicant's response and withdrawn.

4. ***Enablement Rejection***

Claims 9-13, 15, & 26-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of identifying herbicidally active substances using a polypeptide having sucrose-6-phosphate phosphatase activity encoded by DNA (or polynucleotide) molecules of SEQ ID NO: 1, does not reasonably provide enablement for a method of identifying herbicidally active substances using variant polypeptides encoded by DNA (or polynucleotide) molecules wherein DNA sequence is 55% (or 69% or 73% or derivative thereof) identical to SEQ ID NO: 1 or functional equivalent thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The scope of the claims does not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties,

predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide sequence(s) of SEQ ID NO: 1 or 3 [*Nicotiana tobacum*] or SEQ ID NO: 5 [*Solanum tuberosum*] and the encoded amino acid sequence of SEQ ID NO: 2 or 4 or 6.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass all modifications of DNA of SEQ ID NO: 1 or a DNA by 45% (or 31% or 27% or derivative thereof), because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting sucrose-6-phosphate phosphatase activity; (B) the general tolerance of sucrose-6-phosphate phosphatase to modification and extent of such tolerance; (C) a rational and predictable scheme for

modifying any sucrose-6-phosphate phosphatase residues with an expectation of obtaining the desired enzymatic or functional equivalent capable of catalyzing a defined chemical reaction using known substrates; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of exact nature of the encoding DNA (or polynucleotide) encoding a specific sucrose-6-phosphate phosphatase of known substrate specificity having the desired enzymatic characteristics to be used in the instant method is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Applicants argue that the instant specification provide considerable direction and guidance in the specification and have presented working examples such that it is well within the level of ordinary skill in the art to practice the claimed invention without undue experimentation. For example, the specification discusses sucrose-6-phosphate phosphatase encoding sequences, such as SEQ ID NO: 1, as well as functional equivalents and variants having 55% sequence identity or greater. See, e.g. Specification, at page 4, lines 19-25 and page 10, line 20 through page 11, line 7. The specification also discloses methods for screening such sequences for sucrose-6-

phosphatase activity, and provides working examples of the cloning, expression, and characterization of sucrose-6-phosphatase encoding sequences. See, e.g., Specification, at page 31, line 44 through page 33, line 2 and page 47, line 5 through page 51, line 34. For example, the specification provides an example for determining sucrose-6-phosphate phosphatase enzyme activity from protein extracts from recombinant E. coli expressing *Nicotiana tobacum* sucrose-6-phosphate phosphatase by measuring inorganic phosphate liberated in reactions with sucrose-6-phosphate. See, Specification, at page 51, lines 8-34 (Examples 5 and 6). Based on such disclosure, the skilled artisan could readily practice the claimed methods without undue experimentation.

Citing MPEP Applicants argue that "[t]he test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue." MPEP § 2164.01 (citing *In re Angstadt*, 537 F.2d 498,504, 190 USPQ 214, 219 (CCPA 1976)). In addition, "the fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation." Id. (citing In re Certain *Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm"n 1983), *affd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985)).

Accordingly, the specification enables the claimed invention without undue experimentation. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 9-13, 15, 17 and 20 under 35 U.S.C. § 112, first paragraph.

Applicants response is considered but not found to be persuasive because the availability of sucrose-6-phosphate phosphatase enzyme sequences in the prior art having close sequence homology the sequences being used in the method claims does not provided guidance to modification of sequence of SEQ ID NO: 1, for example, say to the extent of 45%. While the level of skilled artisan is high in making reasonable extent of modifications for sucrose-6-phosphate phosphatase variants, the experimentation necessary to modify the sequences to the extent claimed and use in the method for identifying herbicidally active compound is undue and will involve high unpredictability in view of lack of clear cut working examples as well as no guidance to the factors A-D outlined in the enablement rejection. The rejection is therefore maintained.

9. ***Claim Rejections - 35 USC § 112*** (second paragraph)

Claims 9-13, 15, & 26-27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-13, 15, 17 & 20 in an independent or dependent manner recite the phrase 'derived from amino acid sequence' which is vague and indefinite. The phrase is vague and indefinite because no derivatives of SEQ ID NO: or 2 are disclosed. Deletion of the phrase is suggested to overcome this rejection.

Further, claim 9 (b), recites a nucleic acid molecule having a nucleic acid sequence which, on the basis of the degeneracy of the genetic code, can be derived from the amino acid sequence of SEQ ID NO: 2. This language is repeated in other sections of claim 9 as well as several other claims.

Degeneracy is with reference to the existence of two or more synonym codons for a given amino acid. The claim is confusing in the manner recited - on the basis of the degeneracy of the genetic code, can be derived from the amino acid sequence of SEQ ID NO: 2. See suggested allowable claim language to overcome this part of the rejection.

10. Suggested Allowable claim language (example - claim 9)

Claim 9. A method of identifying herbicidally active compounds, comprising:

i. bringing an isolated polypeptide with the biological activity of a sucrose-6-phosphate phosphatase encoded by a nucleic acid sequence molecule, wherein the nucleic acid molecule is:

a) a nucleic acid sequence of SEQ ID NO: 1;

b) a nucleic acid sequence differing from the nucleic acid sequence of (a) above in codon sequence due to degeneracy of the genetic code; and

c) a nucleic acid sequence which has at least 95% identity with SEQ ID NO: 1, and wherein the nucleic acid sequence encodes a polypeptide having sucrose-6-phosphate phosphatase activity;

d) a nucleic acid molecule which encodes a polypeptide having the sequence of SEQ ID NO: 2.

e) a nucleic acid molecule which encodes a polypeptide sequence, wherein the polypeptide sequence has at least 95% identity with SEQ ID NO: 2, and wherein the nucleic acid sequence encodes a polypeptide having sucrose-6-phosphate phosphatase activity;

into contact with one or more test compounds under conditions which permit the test compound(s) to bind to the nucleic acid molecule or to sucrose-6-phosphate phosphatase; and

ii. detecting whether the test compound binds to the sucrose-6-phosphate phosphatase of i); or

iii. detecting whether the test compound reduces or blocks the transcription, translation or expression of the sucrose-6-phosphate phosphatase activity of i).

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Status of the claims:

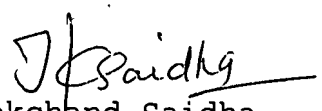
(1) Claims 9-13, 15, & 26-27 are present.

(2) Claims 9-13, 15, & 26-27 (SEQ ID NO: 1 & 2) are rejected.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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